

1251409

UNITED STATES PATENT AND TRADEMARK OFFICE

"TUD AND TUD, WE DO IT THESE PRESENTS, SEAL, CERTIFY:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

November 19, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.

APPLICATION NUMBER: 60/509,377

FILING DATE: *October 07, 2003*

RELATED PCT APPLICATION NUMBER: PCT/US04/33049

Certified by



Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office

Please type a plus sign (+) inside this box →

PTO/SB/16 (8-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Name (first and middle [if any]) Bharat A.	Family Name or Surname Mehta	Residence (City and either State or Foreign Country) Bloomfield Hills, Michigan
<input type="checkbox"/> Additional inventors are being named on the <input type="text"/> separately numbered sheets attached hereto		
TITLE OF THE INVENTION (280 characters max) EMBOLECTOMY CATHETER		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input type="checkbox"/> Customer Number <input type="text"/> → <input type="text"/> Place Customer Number Bar Code Label here		
OR <input type="text"/> Type Customer Number here		
<input checked="" type="checkbox"/> Firm or Individual Name KOHN & ASSOCIATES		
Address 30500 Northwestern Highway		
Address Suite 410		
City Farmington Hills	State Michigan	ZIP 48334
Country US	Telephone (248) 539-5050	Fax (248) 539-5055
ENCLOSED APPLICATION PARTS (check all that apply)		
<input checked="" type="checkbox"/> Specification Number of Pages <input type="text" value="7"/> <input type="checkbox"/> CD(s), Number <input type="text"/>		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets <input type="text" value="2"/> <input checked="" type="checkbox"/> Other (specify) <input type="text"/> Acknowledgement postcard		
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees		
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number <input type="text" value="11-1449"/>		
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.		
<input checked="" type="checkbox"/> No.		
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: <input type="text"/>		
Respectfully submitted, SIGNATURE  TYPED or PRINTED NAME Amy E. Rinaldo TELEPHONE (248) 539-5050		
Date 10/7/03 REGISTRATION NO. 45,791 (if appropriate) Docket Number. 1059.000075		

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (8-00)

Approved for use through 10/31/2002, OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket Number	1059.00075	Type a plus sign (+) inside this box →
---------------	------------	---

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle if any)	Family or Surname	Residence (City and either State or Foreign Country)
		<p>CERTIFICATE OF MAILING BY "EXPRESS MAIL" EV 338883 017 US "EXPRESS MAIL" Mailing Label Number _____</p> <p>Date of Deposit <u>10-7-03</u> I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.</p> <p> _____ (Signature of person mailing paper or fee)</p>

Number 2 of 2

**WARNING: Information on this form may become public. Credit card information should not
be included on this form. Provide credit card information and authorization on PTO-2038.**

Attorney Docket No: 1059.00075

Express Mail Number: EV 338 883 017 US

PROVISIONAL PATENT APPLICATION

5

EMBOLECTOMY CATHETER

BACKGROUND OF THE INVENTION

10

TECHNICAL FIELD

The present invention relates to a catheter. More specifically, the present invention relates to an embolectomy catheter.

15

BACKGROUND ART

A thrombus is a clot of blood formed within a blood vessel and remains attached to its place of origin. An embolism is the obstruction of a blood vessel by a foreign or abnormal particle. The occasion of such a thrombosis or 20 embolism within hospitalized patients is one of the leading causes of death.

A number of different embolus extraction devices have been proposed over the past few years. U.S. Pat. No. 4,406,671 to Weinrib, shows a catheter with a coiled tip section that is arranged for insertion into a blood vessel. This coil is linearly stretchable, so as to minimize its outside diameter, and when 5 pulled proximally through an embolus, is expected to scoop clot material from the blood vessel.

A further device is shown in U.S. Pat. No. 4,762,130 to Fogarty et al., showing a catheter with a corkscrew-like balloon. Removal of the inflated 10 balloon is supposed to remove clot material from the blood vessel within which the helical balloon resides.

A further balloon catheter device is shown in U.S. Pat. No. 5,112,347 to Taheri, which discloses an embolectomy catheter having a balloon on its distal 15 end. A plurality of circumferentially disposed fingers are spaced within the balloon, each finger having a proximal end. The proximal end, when the balloon is deflated, defines a proximally extending scoop, which, during the withdrawal thereof, captures emboli therewithin.

20 It is an object of the present invention to provide an embolectomy catheter which does not utilize a balloon for the retrieval of material from within the blood vessel.

It is yet a further object of the present invention to provide an embolectomy catheter, which permits the distribution of medicaments before, during, or after removal of any clots from a vessel.

5

DESCRIPTION OF THE INVENTION

Generally, the present invention provides an embolectomy catheter and method of using the same. The catheter is very flexible and includes a tip that 10 can have either a rotating or fixed tip cone shape. The parts of the catheter are made of materials known to those of skill in the art that are sufficient to perform the method of the present invention.

The rotating tip/cone head mechanically breaks up the clot/thrombus. 15 The head is made of a material known to those of skill in the art that is sufficient to break up a clot. The head is shown in more detail in the attached drawings.

The present invention comprises an embolectomy catheter, utilizable 20 for the removal of an embolus from a body artery or vein. Such a catheter is made from a polymeric material or other materials known to those of skill in the art.

A detailed description of the embolectomy catheter is set forth in Appendix A included herewith and incorporated by reference in its entirety.

5 Throughout this application, various publications, including United States patents, are referenced by author and year, and patents, by number. Full citations for the publications are listed below. The disclosures of these publications and patents in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the
10 art to which this invention pertains.

The invention has been described in an illustrative manner, and it is to be understood that the terminology that has been used is intended to be in the nature of words of description rather than of limitation.

15

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the described invention, the invention may be practiced otherwise than as specifically described.

APPENDIX A

Embolectomy Catheter

This device is particularly useful for cerebral vasculature, i.e. Basilar artery stem, and Middle central artery or Main stem of Internal carotid artery. Acute thrombosis of cerebral vasculature by an embolus or thrombus is major cause of acute CNS stroke. Currently there are 5 devices in trial using , laser , ultrasound, wire cage device, and venturi catheter etc. These are in addition to trials of thrombolytic agents e.g. TPA, pro-urokinase and low molecular weight Heparin etc.

Currently designed embolectomy devices are rigid, bulky, and very expensive, and they do not have control over distal migration of broken thrombi.

Currently available thrombolytic agents do not consistently lyse the blood clots, due to various different types of clot and their fibrin/platelet content.

Embolectomy catheter concept designed by Dr. B. Mehta of Henry Ford Hospital, offers a new tool to fight the acute stroke. The microcatheter is 2 FR; very flexible, and has a rotating or fix tip cone shape, with grooves on the surface. The cone shaped , grooved head rotates on a corkscrew segment of guide wire. The distal tip of guidewire has a soft hydrophilic expandible plunger which prevents distal migration of macerated fragement.

The rotating tip/cone head mechanically breaks up the clot/thrombus. Besides that the short segment of catheter behind the coupling joint also has grooved outer surface, which also contains perfusion sideholes.

The catheter can be perfused by saline or mixture of thrombolytic agents in a spray fashion.

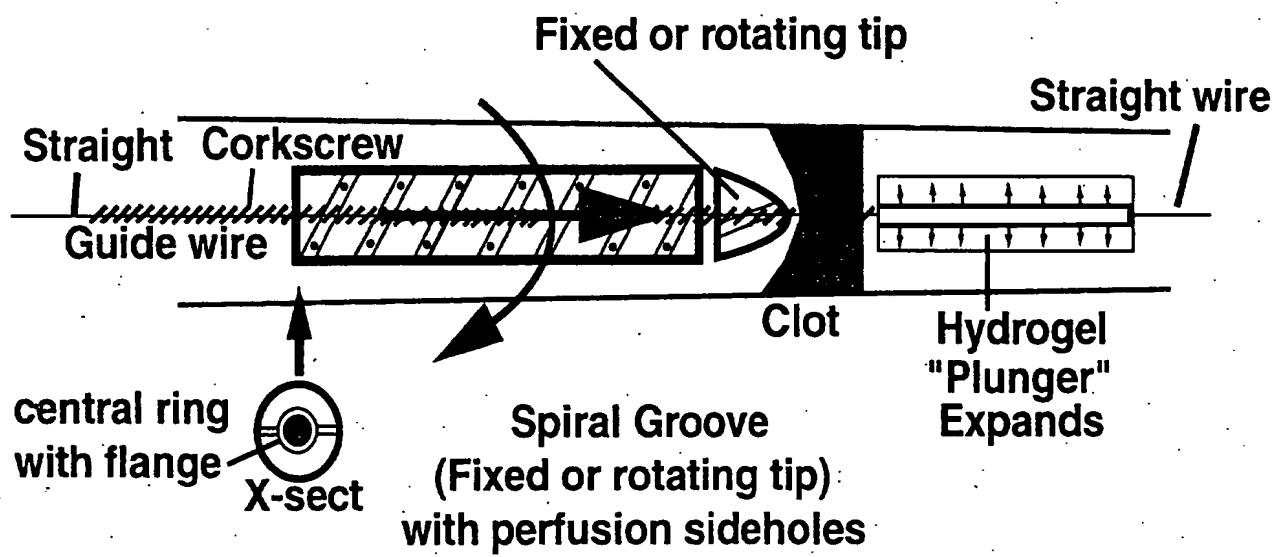
This device makes use of mechanical and chemical agents to dissolve the thrombus and hydrogel plunger prevents distal migration. Vigorous suction by co-axial 6FR. Catheter and withdrawal of the entire device with fully hydrated hydrogel plunger will bring back the undesirable blood product back into the co-axial catheter, with maintenance of patency of previously occluded artery.

Multiple roles played by this flexible device has a significant potential for a marketable medical device. Although primarily designed for central vasculature, the device can be safely utilized in other organs e.g. coronary artery or limb vessels.

If successfully designed and produced, there are vendors available to produce prototype models for animal trials.

Market - commercial potential is significant because of simplicity of design; multi-task application and prevalence of medical problem at large. More than 50,000 units can be sold per year in U.S. market alone! for treatment of embolectomy in cerebral, coronary and limb vasculature.

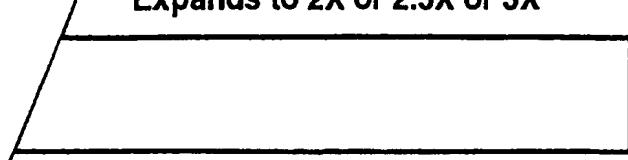
Embolectomy Catheter



Simple Unibody Hydrogel Catheter

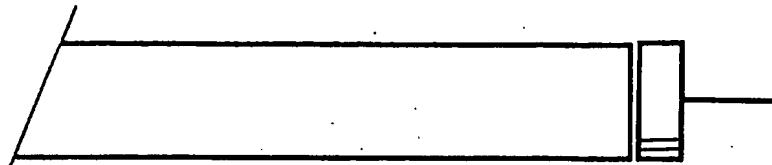
Expands to 2X or 2.5X or 3X

1



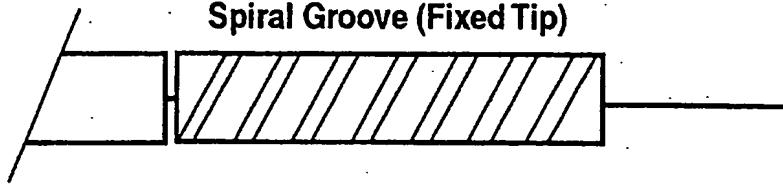
Regular Microcatheter with "Platform Ring" at the top

2



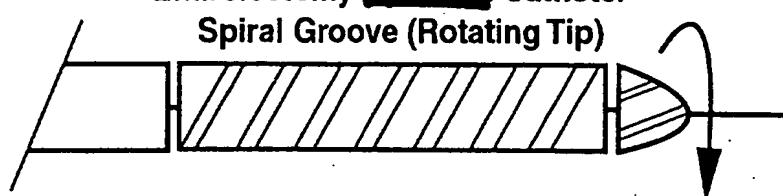
Embolectomy [REDACTED] Catheter
Spiral Groove (Fixed Tip)

3



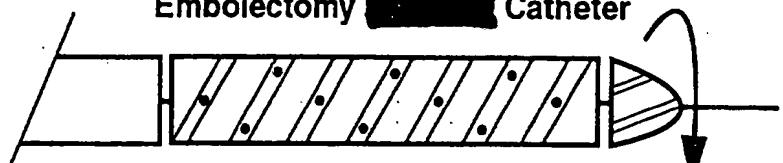
Embolectomy [REDACTED] Catheter
Spiral Groove (Rotating Tip)

4



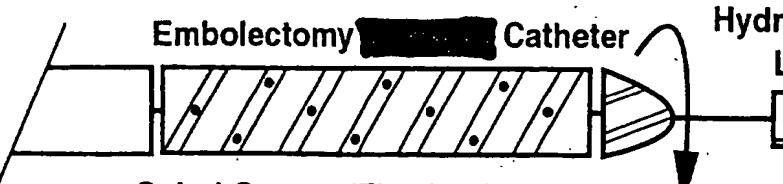
Embolectomy [REDACTED] Catheter

5



Spiral Groove (Fixed or Rotating Tip)
with perfusion sideholes

6



Spiral Groove (Fixed or Rotating Tip)
with perfusion sideholes

Hydrocoil plunger with
Lytic Drugs

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/033049

International filing date: 07 October 2004 (07.10.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/509,377
Filing date: 07 October 2003 (07.10.2003)

Date of receipt at the International Bureau: 26 November 2004 (26.11.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse